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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/177,427	10/22/1998	STEFAN LUKAS	4804-4	3113

7590 10/23/2003

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/23/2003

39

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/177,427

Applicant(s)

LUKAS ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 16-30 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/14/03 has been entered.

Claim Objections

Claims 29-30 are objected to because of the following informalities: Applicant has omitted the term "method" between the words "the" and "of" in both of claims 29-30. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-25, 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (CA 2,068,366) in view of Douglas et al. (5,635,200).

The instant invention is directed toward a formulation comprising particles having a core element containing one or more pharmaceutically active compounds and a substantially continuous polymeric coating thereon, wherein the polymer coating comprises less than 23% of

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the formulation, wherein said core has an aspect ratio of less than 3 and further wherein no more than 25% of the particles are less than 25 micrometers and no more than 2% of the particles are over 250 micrometers.

Morella et al. teach particles comprising a core containing at least one pharmaceutically active ingredient with a continuous coating on the core (abstract) for the purpose of producing a taste-masked free flowing powder. The coating comprises about 10-80% of the formulation (page 4, lines 15-23). The particle size of the core is about 0.1-250 microns, more preferably about 35-125 microns (page 4, line 38-page 5, line 4). The coating thickness is about 0.005-25 microns (page 5, lines 5-10). For paracetamol as the pharmaceutically active ingredient, see page 5, line 16. For ethyl cellulose as the coating, see page 8, lines 21-27). At page 13, lines 1-23, Morella et al. teaches a process of making the particles comprising suspending or dispersing the pharmaceutically active ingredient in the coating solution and spray drying the suspension. See also example 1 at page 17, line 30-page 18, which teaches spray-drying a solution of ethylcellulose and paracetamol. The powder obtained exhibited taste masking and sustained release of the paracetamol. The reference fails to exemplify an aspect ratio of less than 3 and a spherical shape, wherein a spherical particle has an aspect ratio of 1.

While the aspect ratio is not explicitly taught, it is respectfully pointed out that Morella et al. do teach an aspect ratio of less than 3. Since the aspect ratio is a measure of the length compared to the breadth and since Morella et al. teach 0.1-250 microns as the particle size and 0.005-25 microns as the thickness, it is respectfully pointed out that an aspect ratio of less than 3 is taught.

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Douglas et al. teach taste-making compositions of ranitidine. It is taught that the preferred form of the particles is spherical because the presence of irregular shaped particles reduces the effectiveness of subsequent overcoating procedures in masking the bitter taste of the active ingredient. Douglas et al. teach particles in the same size range as those taught by Morella et al. See abstract; Col. 5, line 8-line 15.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify the microcapsules of Morella et al. as having an aspect ratio of 1 (aka a spherical shape), as taught by Douglas et al., because of the expectation of achieving a product that most effectively masks the bitter taste of paracetamol or another active ingredient.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. in view of Douglass et al. as applied to claims 16-25, 27-30. above, and further in view of Lu et al. (4,808,411) or Yajima et al. (5,707,646).

Morella et al. and Douglass et al. are applied as discussed above. The reference lack clarithromycin.

Lu et al. and Yajima et al. both teach that clarithromycin, an antibiotic, has a bitter taste and is suitable for administration in particles that contain a polymer coating in order to provide sustained release and taste-masking. See Col. 4, lines 24-27 and lines 57-61 of Lu et al., and Col. 2, line 25-Col. 4, line 15 of Yajima et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach clarithromycin, as taught by Lu et al. and Yajima et al., as one of the antibiotics of the combined references, because of the expectation of achieving a pharmaceutically acceptable formulation of clarithromycin that is effective in masking its bitter

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taste and because Morella et al. teach that the pharmaceutically active ingredient may be any compound which may be utilized in a taste-masked, sustained/delayed release treatment.

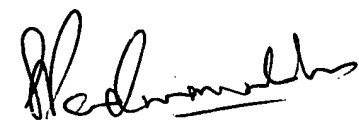
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw


SREENI PADMANABHAN
PRIMARY EXAMINER

9/8/05